



CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1307

[Docket No. CPSC-2014-0033]

Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates

AGENCY: Consumer Product Safety Commission.

ACTION: Availability of Response to Comments and Commission Finding.

SUMMARY: The Consumer Product Safety Commission (Commission or CPSC) is publishing this document in response to a federal court decision remanding the Commission's final phthalates rule, without vacatur, to allow the Commission to address two procedural deficiencies the court found. This document provides notice of the availability of CPSC staff's memorandum responding to public comments on the justification for the phthalates final rule and on the staff's cost-benefit analysis of continuing the interim prohibition on diisononyl phthalate (DINP). This document also provides the Commission's finding that further rulemaking is not warranted at this time.

DATES: [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Susan Proper, Directorate for Economic Analysis, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: (301) 504-7628; email: sproper@cpsc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 108(b)(3) of the Consumer Product Safety Improvement Act of 2008 (CPSIA) required the Commission to promulgate a final rule addressing children's toys and child care articles containing certain phthalates, not later than 180 days after the Commission received a final Chronic Hazard Advisory Panel (CHAP) report. 15 U.S.C. 2057c(b)(3). The Commission was required to "determine, based on such report, whether to continue in effect" the statutory

interim prohibition on children's toys that can be placed in a child's mouth and child care articles "in order to ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety." 15 U.S.C. 2057c(b)(1), (3)(A). Additionally, the Commission was required to "evaluate the findings and recommendations of the Chronic Hazard Advisory Panel and declare any children's product containing any phthalates to be a banned hazardous product under section 8 of the Consumer Product Safety Act (15 U.S.C. 2057), as the Commission determines necessary to protect the health of children." 15 U.S.C. 2057c(b)(3)(B).

On December 30, 2014, the Commission published a notice of proposed rulemaking (NPR) in the *Federal Register*. 79 FR 78324. The NPR stated the Commission proposed to prohibit the manufacture for sale, offer for sale, distribution in commerce, or importation into the United States of any children's toy or child care article containing any of the phthalates specified in the proposed rule. The Commission published a final rule on October 27, 2017, with an effective date of April 25, 2018. 82 FR 49938. The final rule was substantially the same as the proposed rule. The preambles to the NPR and final rule provide detailed discussions of the CHAP report and staff's technical analysis and findings in support of the rule.

In December 2017, the Texas Association of Manufacturers and other parties petitioned the U.S. Court of Appeals for the Fifth Circuit for a review of the CPSC's final phthalates rule. In March 2021, the court remanded the phthalates final rule to the CPSC to address two procedural deficiencies the court found. *Tex. Ass'n. of Mfrs. v. CPSC*, 989 F.3d 368 (5th Cir. 2021). As relevant here, the court held that the final rule failed to: (1) provide adequate notice and comment regarding a change in the primary justification from the proposed rule to the final rule; and (2) consider the costs and benefits of continuing the interim prohibition on DINP as a permanent prohibition. Because the court did not vacate the final rule, the rule has remained in effect since 2018.

II. Staff's Response to Comments

In March 2022, the Commission published a request for comment from the public regarding the two procedural deficiencies the court found. 87 FR 16635 (March 24, 2022). The notice sought public comment on the justification for the final rule, and on the staff's costs and benefits analysis (CBA) regarding continuing the statutory interim prohibition on DINP. CPSC received four public comments (excluding duplicates). The commenters were:

- The American Chemistry Council (ACC);
- A group consisting of the Natural Resources Defense Council, the Environmental Justice Health Alliance for Chemical Policy Reform, Public Citizen, Coming Clean, Earthjustice, the Campaign for Healthier Solutions, and Breast Cancer Prevention Partners (collectively, NRDC et al.); and
- Two individuals (Maranda and Harding).

Two of the four comments (NRDC et al. and Harding) were largely supportive of the rule and of the staff CBA. Two of the four comments (ACC and Maranda) were critical of the rule and of the staff CBA but did not present new data or information within scope of the notice requesting comments. Based on its analysis of the comments and the scope of the court's remand, CPSC staff recommends no further action is necessary to revise the final rule. Section II of this document provides a brief overview of the in-scope comments received in response to the March 2022 request for comment and staff's responses. The complete staff analysis of the comments, including those outside the scope of the request, can be found in the memorandum, "Staff Responses to Request for Comments on Final Rule: 16 CFR Part 1307 'Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates,'" available at: <https://www.cpsc.gov/s3fs-public/Staff-Responses-to-Request-for-Comments-on-Final-Rule-16-CFR-Part-1307-Prohibition-of-Childrens-Toys-and-Child-Care-Articles-Containing-Specified-Phthalates.pdf?VersionId=RWiDEFGrye2fjla1XFSayKafroEj4C7l>.

A. Comments on Justification for the Phthalates Final Rule

Below are brief descriptions of the comments that were submitted on the issues presented for public input regarding the justification for the final rule, and staff's analysis of those comments.

- NRDC et al. commented that the court remanded the rule to correct procedural issues, not for CPSC to reevaluate the underlying science or examine new data provided after the final rule was issued in 2017. Staff agrees with the commenter that data submitted after the rule issuance in 2017 are not within the proper scope of this proceeding on remand.
- NRDC et al. commented that the data confirm that the rule is necessary to provide a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety. In contrast, ACC and Maranda commented that the data in the administrative record did not support the final rule. Staff responds explaining that the justification for the proposed rule was based, in part, on the CHAP's 2014 finding that 5 percent of infants and 10 percent of pregnant women had a HI greater than one.¹ When the 2017 final rule was issued, phthalate exposures in women of reproductive age—a surrogate for pregnant women--had declined, but some women of reproductive age had a hazard index (HI) greater than one. New data on infants and pregnant women were not available. Staff, therefore, concluded that absent continuation of the interim prohibition, phthalate exposures and risks would be inconsistent with the Commission's statutory obligation to "ensure a reasonable certainty of no harm with an adequate margin of safety." 15 U.S.C. 2057c(b)(3)(A).
- ACC commented that data published by the Centers for Disease Control and Prevention after the final rule was issued undermined the final rule by

¹ Section 108(b)(2)(iii) of the CPSIA directed the CHAP to "examine the likely levels of children's, pregnant women's, and others' exposure to phthalates . . ."

demonstrating declining phthalate exposures in the general population, as well as women of reproductive age. Staff's response explains why the data did not undermine the rule, and instead demonstrated the effectiveness of this and similar rules, and why the data were not relevant to the court's remand.

- Maranda commented that the CHAP proved that DINP is safe. Staff disagrees that the CHAP found that DINP is "safe" and notes that the CHAP specifically recommended that the interim prohibition on DINP be continued.

B. Comments on Cost-Benefit Analysis of Continuing the Interim Prohibition of DINP

Below are brief descriptions of the in-scope comments that were submitted on the staff's analysis of the costs and benefits of continuing the interim prohibition on DINP.

Costs Issues

Comments were submitted on the following issues regarding the costs of continuing the interim prohibition on DINP.

- ACC commented that that the CBA underestimated the likely economic costs of maintaining the interim prohibition on DINP, while NRDC et al. argued that the CBA overestimated the costs. Harding commented that the CBA showed that the prohibition on DINP protects vulnerable populations without significant costs. Staff's response explains why the CBA did not underestimate or overestimate those costs.
- ACC provided alternate "baseline" scenarios to estimate the costs and benefits of the rule, given its allegation that many suppliers currently do not comply with the rule. ACC also stated that CPSC should have considered the costs to suppliers' confiscation and destruction of illegally imported products containing violative levels of DINP. Staff's response notes that the CBA analyzed the costs of compliance with the rule for all applicable suppliers, and the benefits to

consumers and society from the reduced exposure to phthalates resulting from that compliance, which was the scope of analysis required by the court's remand.

- Citing information from the CBA on the cost of reformulation for toy suppliers, ACC commented that there is evidence that DINP is still cost-effective after the CPSIA's interim prohibition because it is being used in toys sold in foreign countries. Staff's response notes that ACC did not provide new information or data on prices of toys or DINP before or after the rule that CPSC could use to quantify the impacts on foreign businesses or importers, which CPSC previously discussed and analyzed in the CBA.
- ACC commented that the rule created a "stigma" around DINP and thus, had a negative impact on markets for other consumer goods, causing consumers to demand DINP-free flooring, for example. NRDC et al. commented that the CBA "appropriately rejects" the notion that the interim prohibition on DINP or the final rule meaningfully affected the general market transition away from phthalates to non-phthalate plasticizers. Staff's response notes that, as discussed in the CBA, consumer opposition to phthalates in consumer products other than toys began before the enactment of the CPSIA and the promulgation of the final rule and has continued to grow after the final rule went into effect, as evidenced by recent state-level legislation that applies to many products outside the scope of CPSC's jurisdiction.
- ACC commented that although the price of toys declined during the interim prohibition, the CPSC did not prove that the rule had no impact on the retail price of toys, because prices could have been even lower absent the rule. ACC suggested that CPSC should have done more analysis of other inputs and production costs that might have impacted the price of toys for consumers. NRDC et al. generally expressed support for the analysis in the CBA that

continuation of the interim prohibition on DINP had no measurable impact on the prices for either DINP or toys. Staff's response notes that ACC did not provide any specific data showing that other input or production costs changed, or that such changes increased the price of toys to U.S. consumers. Furthermore, the CBA did not state that the rule had no impact on the price of toys, but rather, assessed that "the impact was minor, both in absolute terms and compared to other impacts on the market." No commenters representing consumers stated that the interim prohibition had raised the price of toys or child care articles, nor did any toy or child care article importers provide such comments.

- ACC commented that there may have been additional negative effects on the market for phthalates and plasticizers that CPSC failed to analyze. Staff's response notes that commenters did not provide any new information to support or counter the analysis in the CBA, which noted that there might be additional, non-quantifiable effects on the markets for both plasticizers and toys.
- Two commenters, ACC and NRDC et al., commented on CPSC's characterization of the consistency of the final rule with state and international regulations and laws. ACC indicated that staff overstated the consistency with other regulations, some of which apply only to mouthable toys, while NRDC et al. commented that the analysis was correct. Staff's response notes that commenters did not provide new information on this subject, or how it would impact the costs of toys, and that the CBA did not claim the final rule was identical to regulations in other states and countries, but rather, that the rule was largely consistent.
- NRDC et al. stated in their view, that CPSC did not need to conduct a cost-benefit analysis, because the CPSIA's requirement that the final rule provides a "reasonable certainty of no harm . . . with an adequate margin of safety," made no mention that cost should be a criterion. Staff's response notes that the court's

decision found that the agency is required to conduct a cost-benefit analysis for the final rule regarding whether to continue the interim prohibition on DINP.

Benefits Issues

Below are brief descriptions of the in-scope comments that were submitted on the benefits analysis in the CBA, and staff's responses.

- Two commenters, NRDC et al. and Harding, found the analysis of benefits generally persuasive. Two commenters, ACC and Maranda, found the estimates generally unpersuasive. Staff's response notes that no commenter provided new data on benefits that was within the scope of consideration, such as different data about the medical costs of treating Testicular Dysgenesis Syndrome (TDS) and explained how the CBA addressed the commenters' concerns.
- ACC commented that the CPSC should have used different data and models to estimate benefits and that the CHAP report was "dated" and should not have been used as the basis for the CBA; nor should CPSC have used the 2013-14 National Human Health and Nutrition Survey (NHANES) data when more recent 2017-18 data are available. NRDC et al. pointed out that the court stated that the CPSC's decision to use the 2013-14 data, and to protect the 99th percentile from harm, is consistent with CPSC's mandate to "ensure a reasonable certainty of no harm." 15 U.S.C. 2057c(b)(3)(A). Staff's response notes that CPSC based its benefits estimate on the CHAP as required by the CPSIA, and on the data available at the time of the final rule. Staff asserts that data on phthalate exposure after the rule was published are not relevant to the rule's analysis of harm caused by the phthalate exposure, as noted above. The CHAP focused on TDS as the toxicity endpoint for phthalate exposure; therefore, the benefits analysis focused on the benefits of reducing the incidence of TDS. The CBA discusses in detail other

peer-reviewed literature that quantified the harm of other toxicity endpoints for phthalate exposure.

- NRDC et al. agreed with staff that reduced cases of TDS are the “essential benefit” of making the interim prohibition permanent; thus, it was appropriate that the CBA benefits section focuses on the estimated cost per case of TDS and the costs to society of TDS caused by phthalate exposure from children’s toys that can be placed in a child’s mouth and child care articles. ACC noted that the CBA referenced various peer-reviewed journal articles that discussed other potential adverse health effects, in addition to TDS, from phthalate exposure. ACC urged CPSC to quantify these effects, rather than allegedly just suggest that these unquantified impacts provide further evidence that the benefits exceed the costs of the final rule. Commenter Harding found the exposure data used to justify the final rule was “weak and insufficient,” but also noted that “the rule would significantly decrease the exposure of medically vulnerable people like children and pregnant women to the dangerous phthalate without impacting the economy.” Commenter Maranda stated: “because the evidence found is not substantial enough the Commission should reject this proposed rule,” and further asserted that “the CHAP has proven DINP to be safe again and again.” Staff’s response notes that none of the comments presented new, in-scope data that are relevant to the estimated benefits of the final rule, such as a quantitative estimate of the contribution of DINP to the cumulative impact of other endocrine-disrupting chemicals, a quantitative estimate of other negative health impacts of DINP exposure, the number of cases of TDS caused by DINP exposure, or different estimates of the cost per case. Staff disagrees with Maranda’s assertion that the CHAP found DINP to be “safe.”

- NRDC et al. commented that although the CBA discussed disparate impacts in the benefits analysis, CPSC should “explicitly consider the environmental justice benefits of addressing these historic and continuing disproportionate impacts when weighing the benefits and costs of continuing the DINP ban.” Staff’s response notes that the commenter did not provide additional data to analyze environmental justice benefits but noted in the CBA that phthalate exposures appear to be higher in infants, children, and women from Black, non-Hispanic populations, and populations living in poverty than persons in other groups, and therefore, the rule may disproportionately benefit persons from vulnerable populations. Staff also notes that the regulation offers the same protection from DINP exposure from new toys and child care articles to all consumers, and there are no exceptions to the rule for small suppliers or for inexpensive items.
- ACC commented that the primary exposure to DINP from toys and childcare articles may be from exposure to phthalates in household dust, rather than through mouthing, and that the CBA should have analyzed the benefits from reducing this type of exposure. Staff’s response notes that the CBA based the analysis of benefits on the findings of the CHAP and that the CHAP did analyze household dust as a source of phthalate exposure for women, infants, and children.

C. Out-of-Scope Comments

The Commission’s March 2022 *Federal Register* notice stated that only comments submitted regarding the rationale for the final rule and/or the cost-benefit analysis of continuing the DINP interim prohibition will be considered, and that comments submitted on any other issues are out of scope and will not be considered. Staff’s memorandum notes that most of the issues raised by commenters did not address the rationale used to justify the final rule, or they repeated comments that were previously submitted on the proposed rule and considered and addressed at that time. Similarly, the comments on the staff CBA either raised information that

staff included in the CBA or suggested that the CBA should have considered out-of-scope issues other than costs of compliance with a continued prohibition on DINP or the associated benefits to consumers, such as the rule’s impact on foreign companies that deliberately violate it. More specific responses to out-of-scope comments can be found in the memorandum “Staff Responses to Request for Comments on Final Rule: 16 CFR Part 1307 “Prohibition of Children’s Toys and Child Care Articles Containing Specified Phthalates”” available at <https://www.cpsc.gov/s3fs-public/Staff-Responses-to-Request-for-Comments-on-Final-Rule-16-CFR-Part-1307-Prohibition-of-Childrens-Toys-and-Child-Care-Articles-Containing-Specified-Phthalates.pdf?VersionId=RWiDEFGrye2fjlalXFSayKafroEj4C7l>.

III. Commission Finding Regarding Need for Further Rulemaking

The court’s remand directed that: “The Commission must allow industry to comment and consider the new justification for the Final Rule. Further, it must consider the costs of continuing Congress’s interim prohibition on DINP to determine whether the rule is ‘reasonably necessary’ to protect from harm.” *Tex. Ass’n. of Mfrs.*, 989 F.3d at 389-90.

CPSC has taken the following actions in response to the court’s remand. CPSC staff drafted a CBA regarding continuing the interim prohibition on DINP. In March 2022, the Commission published a *Federal Register* notice requesting public comment regarding the change in the primary justification from the proposed rule to the final rule, and on staff’s CBA assessing a continuation of the interim prohibition on DINP. The Commission is publishing this document to provide public notice of the availability of staff’s response to comments and the Commission’s finding that further rulemaking is not necessary.²

The March 2022 notice specifically stated comments were being solicited on only the two specific issues remanded by the court, and that “Comments submitted on any other issues are out of scope and will not be considered.” 87 FR at 16636. The Commission adheres to the path charted by the court, considering only the specific issues raised in the court’s remand. Therefore,

² The Commission voted 4-0 to approve publication of this notice.

comments that raise issues beyond the scope of the remand are rejected as being outside the scope of this proceeding.³

As described in Section II of this document, staff considered and responded to the comments received in response to the March 2022 public notice. The Commission has considered the comments submitted in response to the March 2022 notice and the CPSC staff's assessment of those comments and does not find any of the comments submitted to be persuasive such that it would justify a change to the phthalates final rule. Therefore, the Commission determines that no further rulemaking activity to revise the phthalates final rule is warranted. Having considered the issues identified by the court on remand, and the record generated in response to the court's remand, the Commission considers the matter concluded.

Alberta E. Mills,
Secretary, Consumer Product Safety Commission

[FR Doc. 2022-25811 Filed: 12/2/2022 8:45 am; Publication Date: 12/5/2022]

³ Staff nevertheless provided substantive responses to many of the out-of-scope comments, which the Commission adopts to the extent the comments might be deemed relevant.